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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,451	06/25/2002	John Michael Beals	X-12553	8155

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EXAMINER	
MAYER, SUZANNE MARIE	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/856,451	BEALS ET AL.	
	Examiner	Art Unit	
	Suzanne M. Mayer, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 33-59 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 33-59 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 33(a), 46-50 and 52-59, drawn to a non-glycosylated erythropoietin with five glutamate substitutions at positions 24, 38, 83, 88 and 126; it's corresponding DNA and methods of making the protein in cells, and a process of using the protein.

Group II, claims 33(b), 46-50 and 52-59, drawn to a non-glycosylated erythropoietin with an added methionine and arginine at the beginning; it's corresponding DNA and methods of making the protein in cells, and a process of using the protein.

Group III, claims 33(c), 46-50 and 52-59, drawn to a non-glycosylated erythropoietin with methionine and arginine added at the beginning and also a glutamate substitution at residue 88; it's corresponding DNA and methods of making the protein in cells, and a process of using the protein.

Group IV, claims 33(d), 46-50 and 52-59, drawn to a non-glycosylated erythropoietin with added methionine and arginine at the beginning and also a lysine substitution at residue 88; it's corresponding DNA and methods of making the protein in cells, and a process of using the protein.

Group V, claims 33(e), 46-50 and 52-59, drawn to a non-glycosylated erythropoietin with added methionine and arginine at the beginning and also a proline substitution at residue 88; it's corresponding DNA and methods of making the protein in cells, and a process of using the protein.

Group VI, claims 33(f), 46-50 and 52-59, drawn to a non-glycosylated erythropoietin with added methionine and arginine at the beginning and also a serine substitution at residue 88; it's corresponding DNA and methods of making the protein in cells, and a process of using the protein.

Group VII, claims 33(g), 46-50 and 52-59, drawn to a non-glycosylated erythropoietin with added methionine and arginine at the beginning and also four glutamate

substitutions at residues 76, 88, 139 and 154; it's corresponding DNA and methods of making the protein in cells, and a process of using the protein.

Group VIII, claims 33(h), 46-50 and 52-59, drawn to a non-glycosylated erythropoietin with added methionine and arginine at the beginning and also five glutamate substitutions at residues 24, 38, 83, 88 and 126; it's corresponding DNA and methods of making the protein in cells, and a process of using the protein.

Group IX, claims 33(i), 46-50 and 52-59, drawn to a non-glycosylated erythropoietin with added methionine and arginine at the beginning and also five lysine substitutions at residues 24, 38, 83, 88 and 126; it's corresponding DNA and methods of making the protein in cells, and a process of using the protein.

Group X, claims 33(j), 46-50 and 52-59, drawn to a non-glycosylated erythropoietin with added methionine and arginine at the beginning and also four glutamate substitutions at residues 24, 38, 83 and 126; it's corresponding DNA and methods of making the protein in cells, and a process of using the protein.

Group XI, claims 33(k), 46-50 and 52-59, drawn to a non-glycosylated erythropoietin with added methionine and arginine at the beginning and also four lysine substitutions at residues 24, 38, 83 and 126; it's corresponding DNA and methods of making the protein in cells, and a process of using the protein.

Group XII, claims 33(l), 46-50 and 52-59, drawn to a non-glycosylated erythropoietin that has five glutamate substitutions at residues 24, 38, 83, 88 and 126, and also the deletion of the arginine at position 166; it's corresponding DNA and methods of making the protein in cells, and a process of using the protein.

Group XIII, claims 33(m), 34, 46-50 and 52-59, drawn to a non-glycosylated erythropoietin with added methionine and arginine at the beginning and also the deletion of the arginine at position 166; it's corresponding DNA and methods of making the protein in cells, and a process of using the protein.

Group XIV, claims 33(n), 46-50 and 52-59, drawn to a non-glycosylated erythropoietin with added methionine and arginine at the beginning, a glutamate substitution at position 88 and also the deletion of the arginine at position 166; it's corresponding DNA and methods of making the protein in cells, and a process of using the protein.

Group XV, claims 33(o), 46-50 and 52-59, drawn to a non-glycosylated erythropoietin with added methionine and arginine at the beginning, a lysine substitution at position 88 and also the deletion of the arginine at position 166; it's corresponding DNA and methods of making the protein in cells, and a process of using the protein

Group XVI, claims 33(p), 46-50 and 52-59, drawn to a non-glycosylated erythropoietin with added methionine and arginine at the beginning, a proline substitution at position 88 and also the deletion of the arginine at position 166; it's corresponding DNA and methods of making the protein in cells, and a process of using the protein.

Group XVII, claims 33(q), 46-50 and 52-59, drawn to a non-glycosylated erythropoietin with added methionine and arginine at the beginning, a serine substitution at position 88 and also the deletion of the arginine at position 166; it's corresponding DNA and methods of making the protein in cells, and a process of using the protein.

Group XVIII, claims 33(r), 46-50 and 52-59, drawn to a non-glycosylated erythropoietin with added methionine and arginine at the beginning, four glutamate substitutions at positions 76, 88, 139 and 154 and also the deletion of the arginine at position 166; it's corresponding DNA and methods of making the protein in cells, and a process of using the protein.

Group XIX, claims 33(s), 46-50 and 52-59, drawn to a non-glycosylated erythropoietin with added methionine and arginine at the beginning, five glutamate substitutions at positions 24, 38, 83, 88, and 126 and also the deletion of the arginine at position 166; it's corresponding DNA and methods of making the protein in cells, and a process of using the protein.

Group XX, claims 33(t), 46-50 and 52-59, drawn to a non-glycosylated erythropoietin with added methionine and arginine at the beginning, five lysine substitutions at positions 24, 38, 83, 88, and 126 and also the deletion of the arginine at position 166; it's corresponding DNA and methods of making the protein in cells, and a process of using the protein.

Group XXI, claims 33(u), 36, 46-50 and 52-59, drawn to a non-glycosylated erythropoietin with added methionine and arginine at the beginning, four glutamate substitutions at positions 24, 38, 83 and 126 and also the deletion of the arginine at position 166; it's corresponding DNA and methods of making the protein in cells, and a process of using the protein.

Group XXII, claims 33(v), 35, 46-50 and 52-59, drawn to a non-glycosylated erythropoietin with added methionine and arginine at the beginning, four lysine substitutions at positions 24, 38, 83 and 126 and also the deletion of the arginine at position 166; it's corresponding DNA and methods of making the protein in cells, and a process of using the protein.

Group XXIII, claims 37-43 and 45, drawn to a pegylated erythopoietic protein. For claim 43, ONE protein is to be selected from 33a-33v. This is NOT an election of species.

Group XXIV, claim 51, drawn to a transgenic or chimeric non-human animal. The protein that is expressed in this transgenic animal is restricted to the election of ONE of 33a-33v. This is NOT a species election.

2. The inventions listed as Groups I-XXIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Each group contains a patentably separate product because each sequence of claim 33 is drawn to a different amino acid sequences that are structurally and functionally independent. Thus there is not a single unifying technical feature because there are 22 separate and unique proteins. Groups XXIII and XXIV are also separate patentably distinct products, those being drawn to pegylated erythropoietin and a transgenic animal.

Therefore, the technical feature linking the inventions of Groups I-XXIV does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not differentiate the claimed subject matter as a whole over the prior art. Since according to PCT Rule 13.2 the presence of such a common or corresponding special technical feature is an absolute prerequisite for unity to be established, and given that there does not appear to be any other technical feature common to the claimed subject matter as a whole which might be able to fulfill this role, the currently claimed subject matter lacks unity of invention according to PCT Rule 13.1.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Mayer, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 8.30am to 5.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SMM
20 June 2005

ROBERT A. WAX
PRIMARY EXAMINER
Art Unit 1653